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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,886	07/24/2003	Robert R. Schmidt	UF-155CD3	5539

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EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,886	SCHMIDT ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2006 and 21 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-28 are pending. It is noted that claim 11 was omitted in the originally field claims, and the claims are renumbered accordingly.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claims 1-5, 10, 13-22, 24 and 26-29 under 35 U.S.C. 102(e) as being anticipated by Lightfoot et al (US Patent 5,998,700, filed July 1996) is withdrawn in light of Applicant's arguments about priority.

4. The rejection of claims 1-5, 10 and 13-29 under 35 U.S.C. 102(e) as being anticipated by Lightfoot et al (US Patent 6,329,573, filed July 1996) is withdrawn in light of Applicant's arguments about priority.

5. The rejection of claims 1-4, 10, 13 and 17 under 35 U.S.C. 102(e) as being anticipated by Good et al (US Patent 6,084,153, filed February 1996) is withdrawn in light of Applicant's arguments about priority.

6. The rejection of claims 1-28 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method for increasing or decreasing nitrogen metabolism in plants by transformation with a gene encoding a full-length NADP-dependent glutamate dehydrogenase (NADP-GDH) from *Chlorella sorokiniana* or *Escherichia coli* and plants thereby produced, does not reasonably provide enablement for method for increasing or decreasing nitrogen metabolism in plants by transformation with a gene encoding any glutamate

dehydrogenase or fragments thereof and plants thereby produced is withdrawn in light of Applicant's arguments and the Declarations of Phillip Miller.

7. The rejection of claims 1-28 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicant's arguments and the Declarations of Phillip Miller.

Claim Rejections - 35 USC § 112

8. Claims 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the Office action mailed 13 September 2005, as applied to claims 22-29. Applicant's arguments filed 21 March 2006 have been fully considered but they are not persuasive.

Claim 21 is indefinite for claim "cells". If one had only one such cell, would it be covered under any issued patent? It is suggested that "Transgenic plant cells" be replaced with --A transgenic plant cell--.

Applicant urges that "cells" means more than one cell (response pg 8).

This is not found persuasive because it is not clear if only one cell would be covered by a patent issued on the invention.

Claims 22-28 recite the limitation "transgenic cells according to claim 21" in line 1. There is insufficient antecedent basis for this limitation in the claims, as claim 2 is drawn to transgenic plant cells.

Applicant urges that antecedent basis is found in claim 21 (response pg 8).

This is not found persuasive because claim 21 is drawn to transgenic plant cells. It is suggested that "transgenic cells" in claims 22-28 be replaced with --transgenic plant cells--.

Claim 28 recites the limitation "said tissue specific initiation region" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Applicant urges that the transcription initiation region in claim 27 is tissue specific (response pg 8).

This is not found persuasive. It is suggested that "tissue specific" be deleted from claim 28.

Claim Rejections - 35 USC § 102

9. Claims 1-5 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Long et al (1994, Plant Physiol. 105:115). The rejection is repeated for the reasons of record as set forth in the Office action mailed 13 September 2005. Applicant's arguments filed 21 March 2006 have been fully considered but they are not persuasive.

Long et al teach a method of increasing nitrogen metabolism in plant cells by transformation with a construct encoding a bacterial glutamate dehydrogenase, which would inherently increase the assimilation of inorganic nitrogen (in the form of ammonium) into

organic nitrogen. The GDH is operably linked to a chloroplast transit peptide and the construct comprises a polyadenylation sequence. The coding sequence has been altered to use plant-favored codons. The transformed cells would inherently have increased biomass or carbon/nitrogen levels.

Applicant urges that Long et al is not enabling and fails to provide the artisan with any expectation of success, only an invitation to experiment, as no details are provided by way of DNA sequence information, plasmid source, restriction enzyme information, source organism for the gene, transformation vector or target plant species (response pg 8-9).

This is not found persuasive. The instant claims are drawn to use of any GDH. Plasmid source, restriction enzyme information, source organism for the gene, transformation vector or target plant species are all known to one of skill in the art. Applicant's arguments and evidence in response to the 35 USC 112, 1st rejections demonstrated that a number of bacterial enzymes were known at the time of publication of Long et al, and that any GDH from any source would work in the instant invention.

Applicant urges that Long et al do not tell in which way nitrogen metabolism was altered, and they speculate that it may alter plant growth (response pg 9).

This is not found persuasive because the claims are drawn to either increasing or decreasing nitrogen metabolism.

Applicant urges that Long et al do not identify their bacterial gene or tell how it was altered (response pg 9).

This is not found persuasive. The instant claims are not limited to a GDH from a particular bacteria, and bacterial GDHs were known in the art. Long does teach the alteration of the gene - addition of signal sequences alteration of the 3' non-coding region and adjustment to plant preferred codons, all methods of which were well known in the art at the time Long et al was published.

Applicant urges that there is no teaching that any observable effects were found (response pg 9).

This is not found persuasive. The instant specification shows that observable effects would be obtained.

Claim Rejections - 35 USC § 103

10. Claims 1-5, 8-10, 12-17 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Long et al (1994, Plant Physiol. 105:115). The rejection is repeated for the reasons of record as set forth in the Office action mailed 13 September 2005, as applied to claims 1-5, 8-10 and 13-14. Applicant's arguments filed 21 March 2006 have been fully considered but they are not persuasive.

The claims are drawn to a method of increasing or decreasing nitrogen metabolism in a plant by transformation of a gene encoding GDH.

Long et al disclose a method of increasing or decreasing nitrogen metabolism in plant cells by transformation of a gene encoding GDH, as discussed above. Long et al do not disclose regeneration of those cells into whole plants.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of increasing or decreasing nitrogen metabolism in plant cells by transformation of a gene encoding GDH as taught by Long et al, to regenerate those cells into plants. One of ordinary skill in the art would have been motivated to do so to evaluate the performance of the plants in the field.

Applicant did not separate their arguments with respect to the two rejections under Long et al; they are all addressed above. However, it is noted that only a reasonable expectation of success is required for determinations of obviousness, as taught in *In re O'Farrell*, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988).

11. Claims 1-3, 5, 8, 10, 12-14, 16, 18-22 and 26-28 rejected under 35 U.S.C. 103(a) as being unpatentable over Coruzzi et al (US Patent 6,107,547, filed October 1994).

The claims are drawn to a method of increasing or decreasing nitrogen metabolism in a plant by transformation of a gene encoding GDH.

Coruzzi et al disclose plants transformed with a nucleic acid encoding glutamine synthase. Coruzzi et al do not disclose plants transformed with a nucleic acid encoding GDH.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of increasing nitrogen assimilation as taught by Coruzzi et al, to use a nucleic acid encoding GDH. One of ordinary skill in the art would have been motivated to do so because of the suggestion of Coruzzi et al to do so (column 11, lines 39-47; column 12, lines 3-7). One of skill in the art would operably link the nucleic acid to appropriate expression control sequences, including a promoter and a polyadenylation sequence; these, including seed-

specific and constitutive promoters are also taught by Coruzzi et al (column 13, line 48, to column 14, line 63). Coruzzi et al also suggest transformation of dicot and monocots, including maize (column 17, lines 32-36) and targeting the enzyme to the chloroplast via a chloroplast targeting enzyme to improve nitrogen assimilation (column 11, lines 56-62).

12. Claims 1-5, 8-10 and 12-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coruzzi et al (US Patent 6,107,547, filed October 1994) in view of Long et al (1994, Plant Physiol. 105:115).

The claims are drawn to a method of increasing or decreasing nitrogen metabolism in a plant by transformation with a nucleic acid encoding a bacterial GDH and modification of the nucleic acid to use plant-favored codons.

The teachings of Coruzzi et al are discussed above. Coruzzi et al do not disclose use of a nucleic acid encoding a bacterial GDH.

The teachings of Long et al are discussed above.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of increasing nitrogen assimilation as taught by Coruzzi et al, to use a nucleic acid encoding a bacterial GDH as described in Long et al. One of ordinary skill in the art would have been motivated to do so because selection of the source of GDH is an obvious design choice and because of teaching of Long et al to use a nucleic acid encoding a bacterial enzyme. One of ordinary skill in the art would have been motivated to use plant-favored codons because of teaching of Long et al to do so.

Double Patenting

13. Claims 1-4, 7-8, 10-14, 22 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-9 of U.S. Patent No. 5,879,941. The rejection is repeated for the reasons of record as set forth in the Office action mailed 13 September 2005. Applicant's arguments filed 21 March 2006 have been fully considered but they are not persuasive.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the method for increasing nitrogen assimilation in plants and plant cells, as claimed in the issued patent, has the same steps as the methods for increasing or decreasing nitrogen metabolism in plant cells, and increasing biomass, increasing total protein, increasing total C/N levels, increasing grain density, and increasing plant yield in plants, as claimed in the instant application; *i.e.*, both comprise the steps of transforming a plant cell with a nucleic acid encoding a protein with glutamate dehydrogenase activity and culturing the cells to produce descendent cells expressing the nucleic acid. The method of the issued patent could also be considered a species of the genus of the methods of increasing or deceasing nitrogen metabolism is n a plant, as claimed in the instant application, as evidenced by dependent claim 3 in the instant application. Furthermore, the method of the issued patent is drawn to use of nucleic acids encoding SEQ ID NOs:2, 4, 24 and 26, as is the method of the instant application. Dependent claims in both are drawn to the nucleic acid being operably linked to a plant polyadenylation sequence and to use of a plant expressible promoter.

Applicant urges that they will file a TD when the claims are otherwise indicated as allowable (response pg 10).

This is acknowledged.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Anne Kubelik, Ph.D.
May 24, 2006

ANNE KUBELIK, PH.D.
PRIMARY EXAMINER